



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------|----------------------|----------------------|------------------|
| 10/657,724 | 09/08/2003 | Ian W. Hunter | 0050.2048-006 | 8905 |
| 21005 | 7590 | 12/28/2007 | EXAMINER | |
| HAMILTON, BROOK, SMITH & REYNOLDS, P.C. | | | CAMPBELL, VICTORIA P | |
| 530 VIRGINIA ROAD | | | ART UNIT | PAPER NUMBER |
| P.O. BOX 9133 | | | 4123 | |
| CONCORD, MA 01742-9133 | | | | |
| MAIL DATE | DELIVERY MODE | | | |
| 12/28/2007 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/657,724 | HUNTER, IAN W. | |
| | Examiner | Art Unit | |
| | VICTORIA P. CAMPBELL | 4123 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 October 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 24 and 25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 09 February 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/30/06, 4/25/06, 1/13/05, 6/17/04, 3/19/04.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

This is the initial Office Action based on the 10/657,724 application filed September 8, 2003 which is a continuation of US Application No. 10/656,806, now abandoned, which claimed priority to US Provisional Applications 60/409,090 and 60/424,114. Claims 24 and 25 as elected are currently pending and considered below.

Election/Restrictions

1. Applicant's election without traverse of Invention III (claims 24 and 25) and Species G in the reply filed on October 31, 2007 is acknowledged.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "18" and "82" have both been used to designate the part shown in Figure 13. If the piston (18) and plunger (82) are of significant difference such that they require separate figure numbers, such differences should be indicated in the drawings and separate figures drawn for each component. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because line 5 currently reads “configured stimulate a local surface” but should read --configured to stimulate a local surface--. Correction is required. See MPEP § 608.01(b).
4. The attempt to incorporate subject matter into this application by reference to “The Identification of Nonlinear Biological Systems: Volterra Kernel Approaches” by Korenberg and Hunter is ineffective because subject matter that is not well known in the art can not be presented merely by incorporation by reference.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective.

Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is

the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Claim Objections

5. Claim 25 recites the limitation "the skin sensor" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure related to the tailored stochastic sequence as presented by the applicant does not provide a method or description of how to create said sequence. By definition, stochastic sequences or processes are random or contain a certain degree of probability; the written description gives no direction on how one would obtain a "tailored random" sequence. Additionally, the incorporation by reference of the article "The Identification of Nonlinear Biological Systems: Volterra Kernel Approaches" is improper and therefore not sufficient for enablement.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The tailored stochastic sequence is not a defined characteristic of the invention, therefore any claims that include this subject matter are vague and indefinite. For purposes of examination, the examiner has interpreted "tailored stochastic sequence" as any method that can be used to measure properties of the skin.

10. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite. Claim 25 resides in a different statutory category (The apparatus of claim 24 [...]) from its parent claim. The claim has been treated as a method claim (the statutory category of the parent) in which the device used by the method has been further limited.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,354,273 to Hagen.

24. A method for injecting drug into a biological body comprising: holding a drug (Fig. 1, #14) to be delivered to the body in a drug injector (Col. 4, lines 20-21; Fig. 1, #12); measuring skin properties of the body (Col. 4, lines 55-57; Fig. 1, #27); adjusting the injection pressure of the drug injector with a servo-controller based on the skin properties (Col. 4, lines 40-43; Col. 7, lines 7-10; Fig. 1, #27, 29, 34, 36, 37, 38, 42, 80—all of which work together in a feedback (servo) mechanism); and injecting the drug into the body (Col. 4, line 49-52; Fig. 1, #22).

25. The apparatus of claim 24 wherein the skin sensor measures the properties of the body using a tailored stochastic sequence (Col. 7, lines 3-4; see above 35 U.S.C. 112 second paragraph rejection for claim interpretation).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPN 5,244,461 to Derlien and USPN 5,242,408 to Jhuboo et al feature a similar invention to that presented by applicant, which could be used to perform the method of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123